

Docket No.: CI-0019C4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of :
Randall S. KENT and Edward HORTON :
Serial No.: Continuation App of 09/533,547 :
Filed: October 29, 2003 : Customer No.: 34610
For: METHODS FOR STERILIZING BIOLOGICAL MATERIALS

INFORMATION DISCLOSURE STATEMENT

U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir:

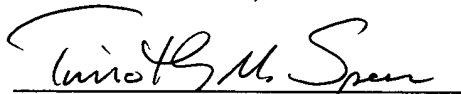
Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- X 4. Copies of the references were cited by or submitted to the Office in parent application No. 09/533,547, filed March 23, 2000, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 C.F.R. §1.98(d).
- X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP



Donald R. McPhail
Registration No. 35,811
Timothy M. Speer

P.O. Box 221200
Chantilly, Virginia 20153-1200
703 502-9440

Date: October 29, 2003

DRM/TMS:dep

Please direct all correspondence to Customer Number 34610

LIST OF PRIOR ART CITED BY APPLICANT SUBSTITUTION FOR (PTO-1449)				ATTY. DOCKET NO. CI-0019C4		APPLN. SERIAL NO. Cont. of 09/533,547		
				APPLICANT Randall S. KENT and Edward HORTON				
				FILING DATE October 29, 2003		GROUP 1744		
U.S. PATENT DOCUMENTS								
*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE	
	A1	RE 23,195	02/1950	Arno Brasch				
	A2	2,832,689	04/1958	Bernard E. Proctor et al.				
	A3	2,920,969	01/1960	E.S. Stoddard				
	A4	2,962,380	11/1960	J.H. Wertheim				
	A5	3,620,944	11/1971	Keiko Tanito				
	A6	3,743,480	07/1973	John D. Falk				
	A7	3,779,706	12/1973	Nablo				
	A8	4,136,094	01/1979	Condie				
	A9	4,251,437	02/1981	Rasmussen et al.				
	A10	4,282,863	08/1981	Beigler et al.				
	A11	4,330,626	05/1982	Blair et al.				
	A12	4,336,247	06/1982	Eriksen				
	A13	4,370,264	01/1983	Kotitschke et al.				
U.S. PATENT APPLICATION PUBLICATIONS								
*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE	
	B1	US2002/0064807 A1	05/30/02	BADYLAK et al.	435	34	11/14/01	
U.S. PATENT APPLICATIONS								
*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS		
	C1							
FOREIGN PATENT DOCUMENTS								
*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D1	2,056,619	10/1991	Canada				
	D2	310 316	04/1989	Europe				
	D3	334 679	09/1989	Europe				
	D4	919 198 A2	06/1999	Europe (Abstract)			X	
	D5	919 198 A3	06/1999	Europe (Abstract)			X	
OTHER ART								
*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)						
	E1	AABB FDA Liaison Meeting, ABC Newsletter, p. 14 (December 12, 1997)						
	E2	Alladine, M.F. et al., γ -Radiation Damage to Starr-Edwards Valves, The Lancet, 1:594 (1968)						
	E3	Alper, T. et al., Protection by Anoxia of the Scrapie Agent and some DNA and RNA Viruses Irradiated as Dry Preparations, J. Gen. Virol., 3:157-166 (1968)						
EXAMINER				DATE CONSIDERED				

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	A14	4,409,105	10/1983	Hayashi et al.			
	A15	4,472,840	09/1984	Jefferies			
	A16	4,620,908	11/1986	Van Duzer			
	A17	4,784,850	11/1988	Abraham			
	A18	4,798,611	01/1989	Freeman Jr.			
	A19	4,865,602	09/1989	Smestad et al.			
	A20	4,931,361	06/1990	Baldeschwieler et al.			
	A21	4,933,145	06/1990	Uchida et al.			
	A22	4,946,648	08/1990	Dichtelmüller et al.			
	A23	4,963,356	10/1990	Calenoff et al.			
	A24	5,000,951	03/1991	Bass et al.			
	A25	5,012,503	04/1991	Nambu et al.			
	A26	5,044,091	09/1991	Ueda et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B2	US2001/0049141 A1	12/06/01	FIKE et al.	435	384	02/13/98

U.S. PATENT APPLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
	C2						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D6	11-216147	08/1999	Japan (Abstract)			X	
	D7	1321420-A	07/1987	Soviet Union (Abstract)			X	
	D8	WO 90/00907	02/1990	PCT Int'l				
	D9	WO 91/16060	10/1991	PCT Int'l				
	D10	WO 95/03071	02/1995	PCT Int'l				

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E4	Alper, T. et al., Does the Agent of Scrapie Replicate Without Nucleic Acid?, Nature, 214:764-766 (1967)
	E5	Alper, T. et al., The Exceptionally Small Size of the Scrapie Agent, Biochemical and Biophysical Research Communications, 22:278-284 (1966)
	E6	Alper, T. et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, J. Gen. Virol., 41:503-516 (1978)

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	A27	5,106,619	04/1992	Wieschahn et al.				
	A28	5,134,295	07/1992	Wälischmiller				
	A29	5,185,371	02/1993	Rubinstein				
	A30	5,226,065	07/1993	Held et al.				
	A31	5,283,034	02/1994	Okrongly et al.				
	A32	5,362,442	11/1994	Kent				
	A33	5,418,130	05/1995	Platz. et al.				
	A34	5,460,962	10/1995	Kemp				
	A35	5,510,122	04/1996	Sreebny et al.				
	A36	5,548,066	08/1996	Leneau et al.				
	A37	5,603,894	02/1997	Aikus et al.				
	A38	5,609,864	03/1997	Shanbrom				
	A39	5,637,451	06/1997	Ben-Hur et al.				
U.S. PATENT APPLICATION PUBLICATIONS								
*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE	
	B3	US2002/0106394 A1	08/08/02	TUCKER et al.	424	423	09/18/01	
U.S. PATENT APPLICATIONS								
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	C3							
FOREIGN PATENT DOCUMENTS								
*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D11	WO 00/25839	03/2000	PCT Int'l (Abstract)			X	
	D12	WO 01/08611A1	02/2001	PCT Int'l (Abstract)			X	
	D13	WO 01/12318A1	02/2001	PCT Int'l				
	D14	WO 01/32107A2	05/2001	PCT Int'l (Abstract)			X	
	D15	WO 01/32110A2	05/2001	PCT Int'l (Abstract)			X	
OTHER ART								
*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)						
	E7	Akkus, O. et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, J. Orthopaedic Research, 19:927-934 (2001) (Elsevier Science Ltd.)						
	E8	Aparicio, S.R. et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, J. Path., 115:147-162 (1975)						
	E9	Baksa, J. et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, Magyar Traumatologia, 19:138-145 (1976)						
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	A40	5,643,464	07/1997	Rhee et al.			
	A41	5,712,086	01/1998	Horowitz et al.			
	A42	5,730,933	03/1998	Peterson			
	A43	5,817,528	10/1998	Böhm et al.			
	A44	5,837,313	11/1998	Ding et al.			
	A45	5,856,172	01/1999	Greenwood et al.			
	A46	5,881,534	03/1999	Ahlqvist et al.			
	A47	5,981,163	11/1999	Horowitz et al.			
	A48	5,986,168	11/1999	Noishiki			
	A49	5,989,498	11/1999	Odland			
	A50	6,010,719	01/2000	Remon et al.			
	A51	6,046,024	04/2000	Burton et al.			
	A52	6,049,025	04/2000	Stone et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B4	US 2002/0188319 A1	12/12/02	MORRIS et al.	606	213	06/10/02

U.S. PATENT APPLICATIONS

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FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D16	WO 01/45720A1	06/2001	PCT Int'l (Abstract)			X	
	D17	WO 01/49219A1	07/2001	PCT Int'l				
	D18	WO 01/72233A1	10/2001	PCT Int'l (Abstract)			X	
	D19	WO 01/72244A1	10/2001	PCT Int'l (Abstract)			X	
	D20	WO 01/91818A1	12/2001	PCT Int'l (Abstract)			X	

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E10	Baldwin, M.L. et al., Irradiation of Blood Components, pp. 10-78 (1992) (American Association of Blood Banks)
	E11	Baquay, C. et al., Radiosterilization of Albuminated Polyester Prostheses, Biomaterials, 8:185-189 (1987)
	E12	Bassin, R.H. et al., Abrogation of Fv-1 ^b Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, Journal of Virology, 26:306-315 (1978) (American Society for Microbiology)

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U.S. PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A53	6,060,233	05/2000	Wiggins			
	A54	6,066,626	05/2000	Yew et al.			
	A55	6,087,141	07/2000	Margolis-Nunno et al.			
	A56	6,120,592	09/2000	Brault et al.			
	A57	6,159,490	12/2000	Deghenghi			
	A58	6,171,549	01/2001	Kent			
	A59	6,187,572	02/2001	Platz et al.			
	A60	6,190,855	02/2001	Herman et al.			
	A61	6,197,207	03/2001	Chapman et al.			
	A62	6,203,544	03/2001	Gotzen			
	A63	6,214,534	04/2001	Horowitz et al.			
	A64	6,235,508	05/2001	Sowemimo-Coker et al.			
	A65	6,258,821	07/2001	Stogniew et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B5	US2003/0068815 A1	04/10/03	STONE et al.	435	325	05/17/02

U.S. PATENT APPLICATIONS

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	C5						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D21	EP 0 808 167 B1	06/05/02	EPO				
	D22	EP 0 820 301 B1	07/24/02	EPO				
	D23	WO 00/28552	05/18/00	PCT				
	D24	WO 00/52031	09/08/00	PCT				
	D25	JP 408098688A	04/16/96	Japan			Abs	

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E13	Beauregard, G. et al., Temperature Dependence of the Radiation Inactivation of Proteins, Analytical Biochemistry, 150:117-120 (1985) (Academic Press Inc.)
	E14	Bedrossian Jr., E.H. et al., HIV and Banked Fascia Lata, Ophthalmic Plastic and Reconstructive Surgery, 7:284-288 (1991) (Raven Press Ltd.)
	E15	Belov, A.A. et al., The Influence of γ -Radiation on Enzyme Activity of Collalitin in the Process of Storage, Radiobiologiia, 30:519-521(1990)

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	E16	Bingci, L., Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human Placenta Collagen, Chinese Medical Sciences Journal, 9:100-103 (1994)	
	E17	Blakeslee, S., Lack of Oversight in Tissue Donation Raising Concerns, The New York Times, Late Edition, pp. 1, 22 (January 20, 2002) (http://query.nytimes.com)	
	E18	Blanchy, B.B. et al., Immobilization of Factor VIII on Collagen Membranes, J. Biomedical Materials Research, 20:469-479 (1986) (John Wiley & Sons, Inc.)	
	E19	Block, S.S., Disinfection, Sterilization, and Preservation,, Fourth Edition, pp. 31-33 (1991) (Lea & Febiger) (Philadelphia)	
	E20	Bogers, A.J.J.C. et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, Thorac. Cardiovasc. Surgeon, 42:337-339 (1994) (Georg Thieme Verlag Stuttgart)	
	E21	Borisova, E.A. et al., Protein Degradation During Interphase Death of Thymocytes Induced by Radation and Dexamethasone, Radiobiologiia, 30:517-519 (1990)	
	E22	Boyer, T.D. et al., Radiation Inactivation of Microsomal Glutathione S-Transferase, The Journal of Biological Chemistry, 261:16963-16968 (1986)	
	E23	Brown, D.R. et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, J. Neurochem., 76:69-76 (2001) (Int'l Society for Neurochem.)	
	E24	Brown, P. et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, Transfusion, 38:810-816 (1998)	
	E25	Brown, P. et al., Effect of Chemicals, Heat and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, J. Infectious Diseases, 145:683-687 (1982) (University of Chicago)	
	E26	Brown, P. et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, Transfusion, 39:1169-1178 (1999)	
	E27	Brown, P., The Risk of Blood-Borne Creutzfeldt-Jakob Disease, Advances in Transfusion Safety Dev. Biol., 102:53-59 (1999)	
	E28	Burwell, R.G., The Fate of Freeze-Dried Bone Allografts, Transplantation Proceedings, 8(Suppl):95-111 (1976)	
	E29	Callegaro, L. et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological Studies, The International Journal of Artificial Organs, 6:91-96 (1983) (Wichtig Editore)	
	E30	Campalani, G. et al., Aortic Valve Replacement With Frozen Irradiated Homografts, Eur. J. Cardio-thorac. Surg., 3:558-561 (1989) (Springer-Verlag)	
	E31	Campbell, D.G. et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, Aust. N.Z. J. Surg., 69:517-521 (1999)	
	E32	Chanderkar, L.P. et al., The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation, Radiation Research, 65:283-291 (1976) (Academic Press, Inc.)	
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*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)	
	E33	Chanderkar, L.P. et al., Radiation-Induced Changes In Purified Prothrombin and Thrombin, Biochimica et Biophysica Acta, 706:1-8 (1982) (Elsevier Biomedical Press)	
	E34	Cheung, D. T. et al., The Effect of γ -Irradiation on Collagen Molecules, Isolated α -chains, and Crosslinked Native Fibers, J. Biomedical Materials Research, 24:581-589 (1990) (John Wiley & Sons, Inc.)	
	E35	Chin, S. et al., Virucidal Treatment of Blood Protein Products With UVC Radiation, Photochemistry and Photobiology, 65:432-435 (1997) (American Society for Photobiology)	
	E36	Chuchalin, A.G. et al., Clinical Immunosorbents Basing on Space-Network Polymers, Bioorg Khim, 14:1524-1529 (1988) (Russia)	
	E37	Cohen, D. J. et al., The Fate of Aortic Valve Homografts 12 to 17 Years After Implantation, Chest, 93:482-484 (1988)	
	E38	Conrad, E. U. et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, J. Bone and Joint Surgery, 77-A:214-224 (1995)	
	E39	Cornu, O. et al., Effect of Freeze-Drying and Gamma Irradiation on the Mechanical Properties of Human Cancellous Bone, J. Orthopaedic Research, 18:426-431 (2000)	
	E40	Dagli, A. S., Correction of Saddle Nose Deformities by Coral Implantation, Eur. Arch. Otorhinolaryngol., 254:274-276 (1997) (Springer-Verlag)	
	E41	Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-.Gamma.-Ray, Radiat. Phys. Chem., 46:4-6 (Caplus Abstract No. 1995:923966) (1995)	
	E42	De Deyne, P. et al., Some Effects of Gamma Irradiation on Patellar Tendon Allografts, Connective Tissue Research, 27:51-62 (1991) (Gordon and Breach Science Publishers S. A.)	
	E43	Di Simplicio, P. et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, Free Rad. Res. Comm., 14:253-262 (1991) (Harwood Academic Publishers GmbH)	
	E44	Donnelly, R.J. et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, Thorax, 28:95-101 (1973)	
	E45	Dyskin, E.A. et al., Hemomicrocirculatory Bed in the Wall of Hollow Organs of the Dog Gastrointestinal Tract at Portal Hypertension, Arkh Anat Gistol Embiol, 93:58-68 (1987)	
	E46	Dziedzic-Goclawska, A. et al., Effect of Radiation Sterilization on the Osteoinductive Properties and the Rate of Remodeling of Bone Implants Preserved by Lyophilization and Deep-Freezing, Clinical Orthopaedics and Related Research, 272:30-37 (1991)	
	E47	Eichler, D.C. et al., Radiation Inactivation Analysis of Enzymes, J. Biological Chemistry, 262:9433-9436 (1987)	
	E48	Elliot, L.H. et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, J. Clinical Microbiology, 16:704-708 (1982) (American Society for Microbiology)	
	E49	Fideler, B. M. et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, American Journal of Sports Medicine, 23:643-646 (1995)	
	E50	Fideler, B.M. et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, J. Bone and Joint Surgery, 76-A:1032-1035 (1994) (The Journal of Bone and Joint Surgery, Inc.)	
	E51	Field, E.J. et al., Susceptibility of Scrapie Agent to Ionizing Radiation, Nature, 222:90-91 (1969)	
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

LIST OF PRIOR ART CITED BY APPLICANT SUBSTITUTION FOR (PTO-1449)		ATTY. DOCKET NO. CI-0019C4	APPLN. SERIAL NO. Cont. of 09/533,547
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OTHER ART			
*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)	
	E52	Ghosh, M.M. et al., A Comparison of Methodologies for the Preparation of Human Epidermal-Dermal Composites, <i>Annals of Plastic Surgery</i> , 39:390-404 (1997) (Lippincott-Raven Publishers)	
	E53	Gibbons, M.J. et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, <i>J. Orthop Res.</i> , 9:209-218 (1991) (Orthopaedic Research Society)	
	E54	Gibbons, J.R.P. et al., Gamma Ray Sterilisation of Homograft Valves, <i>Bulletin De La Societe Internationale De Chirurgie</i> , 3:353-358 (1969)	
	E55	Goertzen, M.J. et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants, <i>Knee Surg. Sports Traumatol. Arthroscopy</i> , 2:150-157 (1994) (Springer-Verlag)	
	E56	Goertzen, M.J. et al., Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon, <i>J. Bone and Joint Surgery</i> , 77-B:205-212 (1995) (British Editorial Society of Bone and Joint Surgery) (Retracted)	
	E57	Gregorczy, S. et al., Strength of Lyophilized and Irradiated Cortical Bone of the Human Femur, <i>Chir. Narz. Ruchu Ortop. Pol.</i> , 60:129-133 (1995)	
	E58	Guidoin, R. et al., A Compound Arterial Prosthesis: The Importance of the Sterilization Procedure on the Healing and Stability of Albuminated Polyester Grafts, <i>Biomaterials</i> , 6:122-128 (1985) (Butterworth & Co Ltd.)	
	E59	Haig, D.A. et al., Further Studies on the Inactivation of the Scrapie Agent by Ultraviolet Light, <i>J. Gen. Virol</i> , 5:455-457 (1969)	
	E60	Hehrlein, F. W. et al., Biochemical Changes in Heterologous Aortic Valve Transplants Following Application of Various Sterilization Methods, <i>Langenbecks Arch Chair</i> , 325:1183-1185 (1969)	
	E61	Hehrlein, F.W. et al., Morphological Studies on Heterologous Heart Valve Transplants Under Various Sterilization Conditions, <i>Thoraxchir vask Chir</i> , 17: 244-251 (1969)	
	E62	Hernigou, P. et al., Radiation Sterilization of Bone and the HIV Virus, <i>Revue de Chirurgie Orthopédique</i> , 79:445-451 (1993) (Masson, Paris)	
	E63	Hiemstra, H. et al., Inactivation of Human Immunodeficiency Virus by Gamma Radiation and its Effect on Plasma and Coagulation Factors, <i>Transfusion</i> , 31:32-39 (1991)	
	E64	Hinton, R. et al., A Biomechanical Analysis of Solvent-dehydrated and Freeze-Dried Human Fascia Lata Allografts, <i>The American Journal of Sports Medicine</i> , 20:607-612 (1992) (Am. Orthopaedic Soc. for Sports Medicine)	
	E65	Horowitz, B. et al., Inactivation of Viruses in a Labile Blood Derivatives, II. Physical Methods, <i>Transfusion</i> , 25:523-527 (1985)	
	E66	Horowitz, M., Sterilization of Homograft Ossicles by Gamma Radiation, <i>J. Laryngology and Otology</i> , 93:1087-1089 (1979)	
	E67	House, C. et al., Inactivation of Viral Agents in Bovine Serum by Gamma Irradiation, <i>Can. J. Microbiol.</i> , 36:737-740 (1990)	
	E68	Hsiue, G. et al., Absorbable Sandwich-Like Membrane for Retinal-Sheet Transplantation, pp.20-25 (2002) (Wiley Periodicals, Inc)	
	E69	Ijiri, S. et al., Effect of Sterilization on Bone Morphogenetic Protein, <i>J. Orthopaedic Research</i> , 12:628-636 (1994) (Orthopaedic Research Society)	
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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GROUP
1744

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E70	Imamaliyev, A.S. et al., Biological Properties of Bone Tissue Conserved in Plastic Material and Sterilized With Gamma Rays, ACTA Chirurgiae Plasticae, 16:129-135 (1974) (Avicenum, zdravotnické nakladatelství)
	E71	Ingegneri, A. et al., An 11-Year Assessment of 93 Flash-frozen Homograft Valves in the Aortic Position, Thorac., Cardiovasc. Surgeon, 27:304-307 (1979) (Georg Thieme Verlag Stuttgart)
	E72	Jensen, J. et al., Membrane-bound Na, K-ATPase: Target Size and Radiation Inactivation Size of Some of Its Enzymatic Reactions, J. Biological Chemistry, 263:18063-18070 (1988) (Am. Soc. for Biochem. and Mol. Biol.)
	E73	Jensen, O. T. et al., Vertical Guided Bone-Graft Augmentation in a New Canine Mandibular Model, The Int'l Journal of Oral and Maxillofacial Implants, 10:335-343 (1995)
	E74	Jerosch, J. et al., A New Technique for Bone Sterilization, Biomed. Technik, 34:117-120 (1989)
	E75	Jerosch, J. et al., Influence of Different Rehydration Periods on the Stability and the Water Content of Bone Allografts After Lyophilization, Gamma-Irradiation, and Lipid Extraction, Z. Orthop., 132:335-341 (1994) (F. Enke Verlag Stuttgart)
	E76	Kamat, H.N. et al., Correlation of Structural Alterations in Bovine Fibrinogen with Loss of Clotting Properties After Gamma Irradiation, Radiation Research, 49:381-389 (1972) (Academic Press, Inc.)
	E77	Katz, R.W. et al., Radiation -Sterilized Insoluble Collagenous Bone Matrix is a Functional Carrier of Osteogenin for Bone Induction, Calcified Tissue Int., 47:183-185 (1990) (Springer-Verlag New York Inc.)
	E78	Keathly, J.D. et al., Is There Life After Irradiation? Part II: Gamma-Irradiated FBS in Cell Culture, BioPharm, (July-August) pp. 46, 50-52 (1993)
	E79	Kempner, E.S. et al., Effect of Environmental Conditions on Radiation Target Size Analyses, Analytical Biochemistry, 216:451-455 (1994)
	E80	Kempner, E.S. et al., Radiation-Damaged Tyrosinase Molecules are Inactive, Biophysical Journal, 55:159-162 (1989) (Biophysical Society)
	E81	Kempner, E.S. et al., Size Determination of Enzymes by Radiation Inactivation, Analytical Biochemistry, 92:2-10 (1979) (Academic Press, Inc.)
	E82	Kerboull, L. et al., In Vitro Study of the Influence of Various Conservation Methods on the Mechanical Properties of Patellar Tendon Allografts, Chirurgie, 117:751-762 (1991) (Masson, Paris)
	E83	Kitchen, A.D. et al., Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins, Vox Sang, 56:223-229 (1989) (S. Karger AG, Basel)
	E84	Komender, A. et al., Some Biological Properties of Bovine Trypsinized Fascia Xenografts, Archivum Immunologiae et Therapiae Experimentalis, 29:485-489 (1981)
	E85	Komendar, A. et al., Some Biological Properties of Preserved Bovine Fascia Enriched With Pulverized Calf Cartilage, Archivum Immunologiae et Therapiae Experimentalis, 32:211-219 (1984)
	E86	Kouvalchouk, J.F. et al., The Use of Sterilized Bone Allografts in Reconstruction After Tumour Resection, Revue de Chirurgie Orthopédique, 72:393-401 (1986) (Masson, Paris)
	E87	Kuijpers, A.J. et al., In vivo Compatibility and Degradation of Crosslinked Gelatin Gels Incorporated in Knitted Dacron, J. Biomed Mater Res., 51:136-145 (2000) (John Wiley & Sons, Inc.)
EXAMINER		DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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GROUP
1744

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E88	Latarjet, R. Inactivation of the Agents of Scrapie, Creutzfeldt-Jakob Disease, and Kuru by Radiations, Slow Transmissible Diseases of the Nervous System, 2:387-407 (1979) (Academic Press, Inc.) (New York)
	E89	Latarjet, R. et al., Inactivation of the Scrapie Agent by Near Monochromatic Ultraviolet Light, Nature, 227:1341-1343 (1970)
	E90	Lee, D.C. et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, Transfusion, 41:449-455 (2001)
	E91	Leitman, S. F. Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, Transfus. Sci., 10:219-232 (1989)
	E92	Le Maire, M. et al., Effects of Ionizing Radiations on Proteins, Journal of Biochem., 267:431-439 (1990)
	E93	License Amendment and Procedures for Gamma Irradiation of Blood Products, Dept. of Health & Human Services, Food and Drug Administration, pp. 1-18 (June 22, 1993)
	E94	Linberg, J.V. et al., Preserved Irradiated Homologous Cartilage For Orbital Reconstruction, Ophthalmic Surgery, 11:457-462 (1980)
	E95	Lüssi-Schlatter, B. et al., Antimicrobial Treatment of Enzyme Preparations With Gamma Rays, Pharm Acta Helv, 49:66-75 (1974)
	E96	McDowell, S., Irradiated Cartilage, Plastic Surgical Nursing, pp. 14-15 (Spring 1988)
	E97	Ma, J.T. et al., Functional Size Analysis of F-ATPase from <i>Escherichia coli</i> by Radiation Inactivation, The Journal of Biological Chemistry, 268:10802-10807 (1993) (The Am. Soc. for Biochem. and Mol. Bio., Inc.)
	E98	Maeda, A. et al., Effects of Solvent Preservation With or Without Gamma Irradiation on the Material Properties of Canine Tendon Allografts, Journal of Orthopaedic Research, 11:181-189 (1993) (Orthopaedic Research Society)
	E99	Maeda, A. et al., Solvent-dried and Gamma-irradiated Tendon Allografts in Rats, The Journal of Bone and Joint Surgery, 80-B:731-736 (1998)
	E100	Malawski, S. et al., The Use of Dry-Freeze Bone Grafts Sterilized by Gamma Rays in Orthopaedic Surgery, Chir. Narz. Ruchu Ortop. Pol., 34:61-68 (1969)
	E101	Malm, J. R. et al., An Evaluation of Aortic Valve Homografts Sterilized by Electron Beam Energy, J. Thoracic and Cardiovascular Surgery, 54:471-477 (1967)
	E102	Malm, J.R. et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, Ann. N. Y. Acad. Sci., 147:740-747 (1969)
	E103	Martindale, The Extra Pharmacopoeia, Glucose, Twenty-ninth Edition, Glucose, p. 1265 (1989) (The Royal Pharmaceutical Society of Great Britain)
	E104	Marton, L.S. et al., Disinfection and Inactivation of the Human T. Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus, The Journal of Infectious Diseases, 151:400-403 (1985)
	E105	Marx, G. Protecting Fibrinogen with Rutin During UVC Irradiation for Viral Inactivation, Photochemistry and Photobiology, 63:541-546 (1996) (American Society for Photobiology)
	E106	The Merck Index, Eleventh Edition, Glucose, pp. 699-700 (1989) (Merck & Co., Inc.)
EXAMINER		DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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GROUP
1744

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E107	Miekka, S.I. et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, <i>Haemophilia</i> , 4:402-408 (1998) (Blackwell Science Ltd.)
	E108	Moore, G.L. et al., Effects of 4000 Rad. Irradiation on the In Vitro Storage Properties of Packed Red Cells, Final Rept., Pub. in <i>Transfusion</i> , 25:583-585 (1985) (Abstract)
	E109	Munting, E. et al., Effect of Sterilization on Osteoinduction, <i>Acta Orthop. Scand.</i> , 59:34-38 (1988)
	E110	Nagrani, S. et al., The Radiation-Induced Inactivation of External Yeast Invertase in Dilute Aqueous Solution, <i>Int. J. Radiat. Biol.</i> , 55:191-200 (1989) (Taylor & Francis Ltd.)
	E111	Nakata, K. et al, Reconstruction of the Lateral Ligaments of the Ankle Using Solvent-dried and Gamma-Irradiated Allogeneic Fascia Lata, <i>The Journal of Bone & Joint Surgery</i> , 82-B:579-582 (2000) (British Editorial Society of Bone and Joint Surgery)
	E112	Nielsen, M. et al., The Apparent Target Size of Rat Brain Benzodiazepine Receptor, Acetylcholinesterase, and Pyruvate Kinase Is Highly Influenced by Experimental Conditions, <i>The Journal of Biological Chemistry</i> , 263:11900-11906 (1988) (The American Society for Biochemistry and Molecular Biology, Inc.)
	E113	Oh, W. et al., Mitral Valve Replacement With Preserved Cadaveric Aortic Homografts, <i>J. Thoracic and Cardiovascular Surgery</i> , 65:712-721 (1973)
	E114	Pardo, M.E.M. et al., Clinical Application of Amniotic Membranes on a Patient With Epidermolysis Bullosa, <i>Annals of Transplantation</i> , 4:68-73 (1999)
	E115	Parizek, J. et al., Duraplasty With Pretreated Freeze-Dried Sterilized Human Dura Mater, <i>Sbor. věd. Prací I.F. UK Hradec. Králové.</i> , 33:135-143 (1990)
	E116	Parizek, J. et al., Ovine Pericardium: A New Material For Duraplasty, <i>J. Neurosurg</i> , 84:508-513 (1996)
	E117	Patel, K. M. et al., Effect of Gamma Radiation and Ethylene Oxide on Papain, <i>Indian J. Pharm. Sci.</i> , 41:81-83 (1979) (The Indian Pharmaceutical Association)
	E118	Pietrucha, K. et al., New Collagen Implant As Dural Substitutue, <i>Biomaterials</i> , 12:320-323 (1991) (Butterworth-Heinemann Ltd.)
	E119	Plavsic, Z. M. et al., Resistance of Porcine Circovirus to Gamma Irradation, <i>BioPharm</i> , pp. 32-34, 36 (April 2001)
	E120	Polezhaev, L.V. et al., Repair of Cranial Defects With Regenerating Bone in Grafting Gamma-Irradiated Bone Filings, <i>Zh Vopr Neifokhir Im N.N. Burdenko</i> , (6):57-60 (1984)
	E121	Pollard, The Effect of Ionizing Radiation on Viruses, pp. 65-7, Chapter 4
	E122	Potier, M. et al., Radiation Inactivation of Proteins: Temperature-Dependent Inter-Protomeric Energy Transfer in Ox Liver Catalase, <i>Biochem. J.</i> , 298:571-574 (1994)
	E123	Prolo, D.J. et al., Composite Autogeneic Human Cranioplasty: Frozen Skull Supplemented With Fresh Iliac Corticocancellous Bone, <i>Neurosurgery</i> , 15:846-851 (1984) (The Congress of Neurological Surgeons)
	E124	Prolo, D.J. et al., Superior Osteogenesis in Transplanted Allogeneic Canine Skull Following Chemical Sterilization, In <i>Clinical Orthopaedics and Related Research; Section III: Basic Science and Pathology</i> , (168):230-242 (1982) (J.B. Lippincott Co.)
	E125	Puolakkainen, P.A. et al., The Effect of Sterilization on Transforming Growth Factor β Isolated From Demineralized Human Bone, <i>Transfusion</i> , 33:679-685 (1993)
EXAMINER		DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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GROUP
1744

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E126	Quaglio, E. et al., Copper Converts the Cellular Prion Protein into a Protease-resistant Species That Is Distinct from the Scrapie Isoform, J. Biological Chemistry, 276:11432-11438 (2001) (The American Society for Biochemistry and Molecular Biology, Inc.)
	E127	Raptopoulou-Gigi, M. et al., Antimicrobial Proteins in Sterilised Human Milk, British Medical Journal, 1:12-14 (1977)
	E128	Rasmussen, T.J. et al., The Effects of 4 Mrad of γ Irradiation on the Initial Mechanical Properties of Bone-Patellar Tendon-Bone Grafts, Arthroscopy: J. Arthroscopic and Related Surgery, 10:188-197 (1994) (Raven Press, Ltd.)
	E129	Reid, B.D., The Sterways Process: a New Approach to Inactivating Viruses Using Gamma Radiation, Biologicals, 26:125-130 (1998) (The Int'l Assoc. of Biological Standardization)
	E130	Ripamonti, U. et al., Long-Term Evaluation of Bone Formation by Osteogenic Protein 1 in the Baboon and Relative Efficacy of Bone-Derived Bone Morphogenetic Proteins Delivered by Irradiated Xenogeneic Collagenous Matrices, J. Bone and Mineral Research, 15:1798-1809 (2000) (Am. Soc. for Bone and Mineral Res.)
	E131	Rittenhouse, E. A. et al., Sterilization of Aortic Valve Grafts for Transplantation, Archives of Surgery, 101:1-5 (1970)
	E132	Roe, S.C. et al., The Effect of Gamma Irradiation on Xenograft Tendon Bioprosthesis, Clinical Materials, 9:149-154 (1992) (Elsevier Science Publishers Ltd.)
	E133	Rohwer, R.G., Estimation of Scrapie Nucleic Acid MW from Standard Curves for Virus Sensitivity to Ionizing Radiation, Nature, 320:381 (1986) (Macmillan Journals Ltd.)
	E134	Rohwer, R.G., Scrapie Infectious Agent is Virus-like in Size and Susceptibility to Inactivation, Nature, 308:658-662 (1984)
	E135	Rohwer, R.G., The Scrapie Agent: "A Virus by Any Other Name", Current Topics in Microbiology and Immunology, 172:195-232 (1991)
	E136	Rohwer, R.G. et al., Scrapie-Virus or Viroid, The Case For a Virus, National Institutes of Neurological and Communicative Disorders and Stroke, NIH, pp. 333-355 (1980)
	E137	Rohwer, R.G., Virus-Like Sensitivity of the Scrapie Agent to Heat Inactivation, Science, 223:600-602 (1984) (American Association for the Advancement of Science)
	E138	Sakai, T. et al., Microbiological Studies on Drugs and Their Raw Materials. IV. ¹⁾ Sterilization of Microbial Contaminants in Enzyme Powder by Gamma Irradiation, Chem. Pharm. Bull., 26:1130-1134 (1978)
	E139	Salehpour, A. et al., Dose-Dependent Response of Gamma Irradiation on Mechanical Properties and Related Biochemical Composition of Goat Bone-Patellar Tendon-Bone Allografts, J. Orthopaedic Research, 13:898-906 (1995)
	E140	Salim-Hanna, M. et al., Free Radical Scavenging Activity Of Carnosine, Free Rad. Res. Comms., 14:263-270 (1991) (Harwood Academic Publishers GmbH)
	E141	Sato, H. et al., Sterilization of Therapeutic Immunoabsorbents by Ionizing Radiation, The International Journal of Artificial Organs, 9:131-136 (1986)
	E142	Schwarz, N. et al., Irradiation-sterilization of Rat Bone Matrix Gelatin, Acta Orthop Scand, 59:165-167 (1988)
	E143	Shcheglova, S.G. et al., The Effect of the Power of Gamma-Radiation on the Radiation dose in the Sterilization of Drugs, Khim Farm ZH, 18:730-732 (1984) Derwent (Abstract) No. 111469
EXAMINER		DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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OTHER ART			
*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)	
	E144	Smith, C.W. et al., Mechanical Properties of Tendons: Changes With Sterilization and Preservation, J. Biomechanical Engineering, 118:56-61 (1996) (ASME)	
	E145	Smith, R.A. et al., Gamma Irradiation of HIV-1, J. Orthopaedic Research, 19:815-819 (2001) (Elsevier Science Ltd.)	
	E146	Song, K.B. et al., Effect of Gamma-irradiation on the Physicochemical Properties of Blood Plasma Proteins, 2002 Annual Meeting and Food Expo-Anaheim, California, Session 30C-1, Food and Chemistry: Proteins, (June 2002) (Abstract)	
	E147	Sullivan, R. et al., Inactivation of Thirty Viruses by Gamma Radiation, Applied Microbiology, 22:61-65 (1971) (American Society for Microbiology)	
	E148	Sung, H. et al., Effects of Various Chemical Sterilization Methods on the Crosslinking and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, Sterilization of Biological Tissues, J. Biomed. Mater. Res., 37:376-383 (1997) (John Wiley & Sons, Inc.)	
	E149	Suomela, H., Inactivation of Viruses in Blood and Plasma Products, Transfusion Medicine Reviews, 7:42-57 (1993) (W.B. Saunders Company)	
	E150	Toritsuka, Y. et al., Effect of Freeze-Drying or γ -Irradiation on Remodeling of Tendon Allograft in Rat Model, J. Orthopaedic Research, 15:294-300 (1997) (Orthopaedic Research Society)	
	E151	Tylman, D., Mechanical Character of Liofilized and Sterilized by γ -Rays Bone Tissue, Chirurgia Narzadow Ruchu Ortop Pol, 31:229-234 (1966)	
	E152	Vaida, R.I. et al., Structural-Functional Peculiarities of Myocardial Capillaries After Resection of the Lungs, Arkn. Anat. Gistol. Embriol., 8:68-73 (1987)	
	E153	Wangerin, K., et al., Behavior of Differently Sterilized Allogenic Lyophilized Cartilage Implants in Dogs, J. Oral Maxillofac Surg., 45:236-242 (1987)	
	E154	Welch, W., A Comparative Study of Different Methods of Processing Aortic Homografts, Thorax, 24:746-749 (1969)	
	E155	White, J.M. et al, Sterilization of Teeth by Gamma Radiation, J. Dent Res., 73:1560-1567 (1994)	
	E156	Wientroub, S. et al., Influence of Irradiation on the Osteoinductive Potential of Demineralized Bone Matrix, Calcified Tissue International, 42:255-260 (1988) (Springer-Verlag New York Inc.)	
	E157	Wong, B. et al., Copper Refolding of Prion Protein, Biochemical and Biophysical Research Communications, 276:1217-1224 (2000) (Academic Press)	
	E158	Wong, B. et al., Differential Contribution of Superoxide Dismutase Activity by Prion Protein <i>in Vivo</i> , Biochemical and Biophysical Research Communications, 273:136-139 (2000) (Academic Press)	
	E159	Wong, B. et al., Prion Disease: A Loss of Antioxidant Function? Biochemical and Biophysical Research Communications, 275:249-252 (2000) (Academic Press)	
	E160	Wyatt, D.E. et al., Is there Life After Irradiation? Part I: Inactivation of Biological Contaminants, BioPharm, pp. 34-39 (June 1993)	
	E161	Yarygina, G.A., Dose Rate Effect on Survival of Microorganisms Used As Test-Cultures in Radiation Sterilization of Medical Products, 9:32-39 (1973) (Radiats Tekh) Caplus Abstract No.2159557 (1973)	
	E162	Zhang, Q. et al., Ethylene Oxide Does Not Extinguish the Osteoinductive Capacity of Demineralized Bone, Acta Orthop Scand, 68:104-108 (1997) (Scandinavian University Press)	
EXAMINER		DATE CONSIDERED	

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OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E163	Zhang, Y. et al., A Comprehensive Study of Physical Parameters, Biomechanical Properties and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery, Spine, 19:304-308 (1994) (J.B. Lippincott Co.)
	E164	(Abstract of EP0919198A2 and EP0919198A3 (Delphion-DERABS Abstract # G1999-304614))
	E165	Website: www.wslfweb.org/docs/dstp2000.dtopdf/19-MD.pdf (Defense Science and Technology Plans, (February 2000) p. 176, Section II, MD.03, U.S. Department of Defense Deputy Under Secretary of Defense (Science and Technology))
	E166	Website: www.usacc.org/ataccc/ppt.html , (Advanced Technology Applications for Combat Casualty Care, 2001 Presentations, US Army Medical Research and Material Command Combat Casualty Care Research Program (2001))
	E167	Website: www.usacc.org/RevisedStepB.html , Bakaltcheva, I. et al., (FY01 Request for Proposals-Intramural-Revised 2, Combat Casualty Care Research Program, (2002))
	E168	Website: www.benvue.com/history/history_content.html , (2002)
	E169	Website: www.phase-technologies.com/html/vol.2no1.html , Jennings, T.A., (Glossary of Terms for Lyophilization) (1999)
	E170	Website: www.phase-technologies.com/html/vol.1no9.html , Jennings, T.A., (Overview of the Lyophilization Process) (1998)
	E171	Website: www.phase-technologies.com/html/vol.1no2.html , Jennings, T.A., (Role of Product Temperature in the Lyophilization Process) (1998)
	E172	Website: www.phase-technologies.com/html/vol.2no2.html , Jennings, T.A., (What I Wish I Knew About Lyophilization) (1999)
	E173	Website: www.phase-technologies.com/html/vol.1no7.html , Jennings, T.A., (Which Shelf Temperature During Lyophilization?) (1998)
	E174	Website: www.phase-technologies.com/html/vol.1no10.html , Jennings, T.A., (Yes, You have no Eutectic) (1998)
	E175	Robert J. Woods, "Food Irradiation," Endeavor, New Series, Vol. 18, No. 3, 1994, pp. 104-108.
	E176	A. Dziedzic-Goclawska et al., "Sterilisation of Tissue Allografts," Advances in Tissue Banking, Vol. 1, pp. 261-321.
	E177	M.J. Goertzen et al., "Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon," Journal of Bone and Joint Surgery (Corrections), Vol. 77-B, No. 2, March 1995, pp. 205-212.
	E178	P.V. Kapanin et al., "Feasibility of liposome cryoradiation sterilization," Khimiko-Farmatsevticheskii Zhurnal, 1988, Vol. 22(4), Abstract, pp. 479-82.
	E179	
	E180	
	E181	
	E182	
EXAMINER		DATE CONSIDERED

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U.S. PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A1	4,994,237	02/19/91	LOGIN et al.	422	21	11/13/89
	A2	6,383,732 B1	05/07/02	STONE	435	1.1	06/01/00
	A3	4,727,027	02/23/88	WIESEHAHN et al.	435	173	10/07/85
	A4	6,312,931 B1	11/06/01	O'DWYER et al.	435	173.1	02/11/00
	A5	6,346,216 B1	02/12/02	KENT	422	22	05/15/00
	A6	6,358,284 B1	03/19/02	FEARNOT et al.	623	23.72	06/02/99
	A7	6,375,989 B1	04/23/02	BADYLAK et al.	424	551	06/10/99
	A8	6,384,419 B1	05/07/02	PURTLE	250	526	03/30/00
	A9	6,461,630 B1	10/08/02	TUCKER et al.	424	423	11/30/99
	A10	6,485,723 B1	11/26/02	BADYLAK et al.	424	93.7	05/08/00
	A11	4,877,866	10/31/89	RUDNICK et al.	530	387	11/18/87
	A12	6,383,810 B2	05/07/02	FIKE et al.	435	384	02/13/98
	A13	5,965,349	10/12/99	LIN et al.	435	2	03/17/97
	A14	5,958,669	09/28/99	OGLE et al.	435	1.1	05/02/97
	A15	5,911,951	06/15/99	GIRARDOT et al.	422	28	02/09/98
	A16	5,002,766	03/26/91	RANSBERGER et al.	424	94.2	09/23/88
	A17	3,962,038	06/08/76	KAWASHIMA et al.	195	68	04/10/74
	A18	4,894,253	01/16/90	HEINEMAN et al.	427	36	08/08/88

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
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U.S. PATENT APPLICATIONS

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	C1						

FOREIGN PATENT DOCUMENTS

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	E2	
	E3	

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